

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF MICHIGAN**

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PERRIGO COMPANY  
AND SUBSIDIARIES,

Case No. 1:17-cv-00737

Plaintiff,

v

**COMPLAINT**

UNITED STATE OF AMERICA,

Defendant.

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Plaintiff, Perrigo Company, on behalf of itself and its consolidated subsidiaries, brings this action and respectfully alleges:

**PRELIMINARY STATEMENT**

1. Plaintiff brings this action pursuant to 28 U.S.C. section 1346(a)(1) and sections 6532 and 7422 of the Internal Revenue Code of 1986 (“IRC”) for the recovery of Federal income taxes, penalties, and interest erroneously and illegally assessed and collected by the Internal Revenue Service (“IRS”), plus statutory interest thereon from the dates of payment. Plaintiff overpaid Federal income taxes for its 52-53 week tax years ending June 27, 2009, June 26, 2010, June 25, 2011, and June 30, 2012 (the “2009 tax year,” “2010 tax year,” “2011 tax year,” and “2012 tax year,” respectively).

2. Plaintiff overpaid taxes, penalties, and interest with respect to transactions involving the purchase, distribution, and sale of store-brand over-the-counter (“OTC”) pharmaceutical products containing the active ingredient omeprazole in the 2009, 2010, 2011, and 2012 tax years.

3. Plaintiff overpaid taxes, penalties, and interest with respect to amounts of legal fees Plaintiff paid or incurred defending against certain patent infringement lawsuits in the 2011 and 2012 tax years.

4. Plaintiff timely filed claims for refund with the IRS for the 2009, 2010, 2011, and 2012 tax years, seeking refunds of Federal income taxes, penalties, and assessed interest, plus interest thereon as allowed by law for each of the years. The IRS disallowed these refund claims and Plaintiff timely files this complaint within the period of limitations provided by IRC section 6532.

5. For the 2009 tax year, Plaintiff claims a refund of tax, penalties, and assessed interest of \$37,221,289, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus statutory interest on the amount to be refunded.

6. For the 2010 tax year, Plaintiff claims a refund of tax, penalties, and assessed interest of \$61,462,133, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus statutory interest on the amount to be refunded.

7. For the 2011 tax year, Plaintiff claims a refund of tax, penalties, and assessed interest of \$40,148,650, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus statutory interest on the amount to be refunded.

8. For the 2012 tax year, Plaintiff claims a refund of tax, penalties, and assessed interest of \$24,730,253, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus statutory interest on the amount to be refunded.

### **PARTIES**

9. Plaintiff is the common parent of an affiliated group of corporations that filed a consolidated Federal income tax return for each tax year at issue in this action. Pursuant to Treasury Regulation section 1.1502-77, Plaintiff is authorized to bring this action on behalf of the entities included in the consolidated group. Plaintiff's principal place of business is and, at all times relevant to this action was, in Allegan, Michigan.

10. Defendant is the United States of America.

### **JURISDICTION AND VENUE**

11. This Court has jurisdiction over this action pursuant to 28 U.S.C. section 1346(a)(1) and IRC section 7422.

12. Venue is proper in this Court pursuant to 28 U.S.C. section 1402(a)(2) because Plaintiff's principal place of business is located within this judicial district.

## **BACKGROUND STATEMENT**

### **Omeprazole**

13. Plaintiff is a leading manufacturer and distributor of store-brand OTC and generic pharmaceutical products.

14. Omeprazole is a proton pump inhibitor useful in treating heartburn, ulcers, and gastro-esophageal reflux disease.

15. Omeprazole base is the active ingredient of Prilosec ("Prilosec Rx"), a patented drug developed by the pharmaceutical company AstraZeneca. Prilosec Rx was first approved and marketed in the United States as a prescription drug in 1989.

16. In 2000, AstraZeneca filed an application with the Food and Drug Administration ("FDA") seeking approval of Prilosec OTC, an OTC version of Prilosec Rx with omeprazole magnesium, rather than omeprazole base, as the active ingredient. Upon obtaining FDA approval in 2003, AstraZeneca began selling Prilosec OTC in the United States. Under FDA regulations, Prilosec OTC became the reference drug for subsequent FDA filings by OTC competitors.

17. Beginning in 2002 and continuing into 2006, Plaintiff attempted to formulate a generic omeprazole product as an alternative to Prilosec OTC ("generic OTC omeprazole") but ultimately was unsuccessful.

18. During 2003 and 2004, Plaintiff also looked to Schwarz Pharmaceutical to formulate generic OTC omeprazole, but Schwarz Pharmaceutical likewise was unsuccessful.

19. During 2005 through 2012, and at all times relevant to this action, L. Perrigo Company ("LPC") was a member of Plaintiff's consolidated group.

20. In August 2005, LPC entered into a Supply & Distribution Agreement (the “Contract”) with Dexcel Pharma Technologies, Ltd. (“Dexcel”), an unrelated Israeli pharmaceutical manufacturer. The Contract related to a potential generic OTC omeprazole product for the United States market that Dexcel was trying to develop and manufacture. As of the date of the Contract, Dexcel had not yet succeeded in developing a generic OTC omeprazole product for the United States market.

21. Under the Contract, Dexcel was responsible for formulating and developing generic OTC omeprazole in tablet form and obtaining FDA approval for the product. If the FDA approved the product, Dexcel would be responsible for manufacturing the product.

22. Under the Contract, if Dexcel succeeded in obtaining FDA approval for generic OTC omeprazole, LPC would be responsible for distributing the product in the United States. LPC agreed to make up to \$600,000 in milestone payments to Dexcel during drug development and also to reimburse Dexcel for up to \$500,000 in litigation expenses incurred in defending against any patent infringement suits brought against Dexcel in connection with the product.

23. The Contract provided that the parties would equally divide net profits from United States sales of the product after certain cost allowances to each party.

24. Perrigo Israel Trading Limited Partnership (“PITLP”) is a partnership organized under the laws of the State of Israel. PITLP was formed in 2006. PITLP was during all relevant years treated as a corporation for United States tax purposes and a partnership for Israeli tax purposes. As a controlled foreign corporation, PITLP is not a member of Plaintiff’s consolidated tax return group.

25. Perrigo LLC (“LLC”) is a limited liability company organized under Delaware law in 2006. LLC was for all relevant years treated as a disregarded entity for United States tax

purposes. PITLP is LLC's sole member, and for United States tax purposes all of the assets, liabilities, and activities of LLC are treated as the assets, liabilities, and activities of PITLP. Henceforth, PITLP and LLC are referred to in this complaint jointly as "PITLP/LLC."

26. PITLP/LLC was formed as part of Plaintiff's intended internationalization of its business operations.

27. PITLP/LLC was formed in accordance with professional tax advice provided to Plaintiff by the global professional services firm Ernst & Young LLP ("EY").

28. PITLP/LLC conducted business activity.

29. PITLP/LLC is a legitimate entity that should be respected for tax purposes and is not a sham.

30. Effective November 29, 2006, LPC and PITLP/LLC entered into an agreement (the "Assignment Agreement") under which LPC assigned its rights and obligations under the Contract to LLC. PITLP/LLC paid LPC \$877,832 as consideration for the assignment. The price paid by PITLP/LLC was based on an economic study prepared by EY.

31. PITLP/LLC and LPC entered into a Sales and Distribution Agreement effective as of November 29, 2006 (the "Sales & Distribution Agreement"). Under the Sales & Distribution Agreement, if approved by the FDA, LPC would distribute Dexcel's generic OTC omeprazole on behalf of PITLP/LLC. The Sales & Distribution Agreement provided LPC with a guaranteed return on its distribution activities and a percentage of the residual profits from the sales of generic OTC omeprazole. The agreed consideration to be paid to LPC was based on an economic study prepared by EY.

32. The Assignment Agreement and Sales & Distribution Agreement each had economic substance and should be respected for tax purposes.

33. The Assignment Agreement shifted ownership of the legal rights and obligations under the Contract from LPC to PITLP/LLC. After the assignment, PITLP/LLC assumed all risks associated with the approval and marketing of the generic OTC omeprazole product.

34. The Assignment Agreement was not an anticipatory assignment of income.

35. The Assignment Agreement and Sales & Distribution Agreement had non-tax business purposes and were entered into consistent with professional advice from EY.

36. In February 2006, Dexcel filed a New Drug Application (“NDA”) with the FDA seeking approval of the generic OTC omeprazole product together with a “Paragraph IV certification” of non-infringement of patents relating to Prilosec Rx. Dexcel filed an NDA, rather than an Abbreviated New Drug Application (“ANDA”), because Dexcel’s generic OTC omeprazole product had a different active ingredient (omeprazole base) than the active ingredient of Prilosec OTC (omeprazole magnesium). Accordingly, a “compare to” statement was not allowed with respect to Prilosec OTC.

37. In May 2006, AstraZeneca sued Dexcel alleging infringement of patents relating to Prilosec Rx. Pursuant to 21 U.S.C. section 355(c)(3)(C), the patent infringement suit filed by AstraZeneca automatically triggered a 30-month stay for FDA approval of Dexcel’s generic OTC omeprazole. Plaintiff was not a party to the AstraZeneca patent infringement lawsuit and generally was barred from any knowledge of the proceedings under the Contract.

38. AstraZeneca and Dexcel settled the patent infringement dispute in September 2007, approximately one year before the expiration of the 30-month stay. The settlement allowed Dexcel to market its generic OTC omeprazole product in the United States upon receipt of FDA approval. Plaintiff was not involved in settlement negotiations between Dexcel and AstraZeneca.

The early conclusion of the patent infringement litigation was unexpected and surprising to Plaintiff.

39. The FDA approved Dexcel's generic OTC omeprazole product for sale in the United States in December 2007.

40. Prior to FDA approval of Dexcel's generic OTC omeprazole product, PITLP/LLC faced the financial obligations imposed by the Contract and considerable risks with respect to whether a generic OTC omeprazole product would be brought to market in the United States, including but not limited to, the risks outside of PITLP's/LLC's control that: (i) the FDA would not approve Dexcel's generic OTC omeprazole tablet; (ii) AstraZeneca, through its patent infringement suit, would block, delay or permanently enjoin sales of Dexcel's generic OTC omeprazole tablet; and (iii) competitors would beat Dexcel to market with a competing generic OTC omeprazole product and significantly reduce available market share. From 2008 onwards, PITLP/LLC faced significant risk that competing omeprazole products would enter the market and erode market share and prices and drive down potential profits from the product.

41. By December 31, 2007, six companies had generic versions of Prilosec Rx on the market. Currently, nine companies produce ten generic versions of Prilosec Rx.

42. Beginning in early 2008, and continuing into subsequent years, Dexcel manufactured generic OTC omeprazole tablets, which were distributed pursuant to the Contract, the Assignment Agreement, and the Sales & Distribution Agreement.

43. During the 52-53 week tax year ending on June 30, 2007 (the "2007 tax year") and the first eight months of the 52-53 week tax year ending on June 28, 2008 (the "2008 tax year"), PITLP/LLC had substantial capital available to it through its parent company, Perrigo



UK FINCO Limited Partnership, a United Kingdom entity treated as a corporation for United States tax purposes.

44. During the last four months of the 2008 tax year, and during the entirety of the 2009-2012 tax years, PITLP/LLC had substantial capital, income, and accounts; was performing under three contracts with unrelated parties; was distributing substantial dividends, and making substantial loans; and was otherwise engaged in substantial business activities. PITLP/LLC also was making payments to Plaintiff for management services, making payments to LPC for marketing and project management services, and making payments to Perrigo Research and Development Company, a member of the Plaintiff's consolidated group, for research and development services.

#### **¶ IV ANDA Litigation Defense Costs**

45. In the ordinary course of its business, Plaintiff incurs legal costs to defend against actual and threatened civil actions alleging that Plaintiff's manufacture and sale of generic pharmaceutical products infringe on another party's rights that are protected under United States patent laws. Under established principles of tax law such patent litigation defense costs are deductible as ordinary and necessary business expenses.

46. In general, a company seeking approval of a new drug must file an NDA with the FDA demonstrating that the drug is safe and effective for the indicated purposes. A company seeking FDA approval to manufacture and sell a generic version of the previously approved drug may file instead an ANDA with the FDA together with a "Paragraph IV certification" of non-infringement for the generic drug (a "¶ IV ANDA"). Compared to an NDA, an ANDA requires a lesser showing that the generic drug for which approval is sought is bioequivalent to the previously approved brand name version of the drug.

47. Upon receiving notice of a ¶ IV ANDA filing, a patent holder may file suit alleging that the proposed generic drug would infringe on the holder's patent rights with respect to a related brand name drug product and cannot be legally sold until the infringed patents have expired.

48. During the 2011 and 2012 tax years, Plaintiff was a named defendant in several patent infringement lawsuits challenging its right to manufacture and sell generic pharmaceuticals that were the subject of ¶ IV ANDAs filed with the FDA. During its 2011 and 2012 tax years, Plaintiff incurred legal fees and expenses to defend against these patent infringement suits. On its Federal income tax returns for these years, Plaintiff deducted as ordinary and necessary business expenses the costs it paid or incurred to defend against patent infringement suits filed in response to ¶ IV ANDA filings.

#### **TAX FILINGS, ADJUSTMENTS, AND CLAIMS**

49. Plaintiff timely filed consolidated Federal income tax returns for its 2007 and 2008 tax years and made payments to the IRS in accordance with the contractual arrangements described above and in the amounts shown on the tax returns for the 2007 and 2008 tax years within the time prescribed by law.

50. The IRS conducted routine civil examinations of Plaintiff's Federal income tax returns for the 2007 and 2008 tax years.

51. In the course of the examination of Plaintiff's 2007 and 2008 tax years, the IRS assigned a skilled international examiner to audit issues associated with Perrigo's international operations and transfer pricing positions.

52. The IRS requested from Plaintiff extensive information regarding the formation, operation, and functions of PITLP/LLC; the relationship between Dexcel and Plaintiff; the

intercompany arrangements between Plaintiff, LPC, and PITLP/LLC; the accounting for intercompany transactions relating to the purchase and sale of generic OTC omeprazole; issues relating to the business purpose, substance and form of PITLP/LLC; pricing of the Assignment Agreement and other issues related to the assignment of the Contract; and transfer pricing reports prepared by EY. In response to the numerous questions and requests for information, Perrigo provided extensive and detailed information to the international specialist.

53. Upon conclusion of its extensive examination of the events, entities and transfer pricing positions with respect to generic OTC omeprazole for Plaintiff's 2007 and 2008 tax years, the IRS did not propose an adjustment to Plaintiff's income or otherwise challenge Plaintiff's tax reporting position. In particular, the IRS did not: (i) propose an income adjustment related to the pricing or substance of the assignment of the Contract; (ii) challenge the conclusion that Plaintiff's transfer pricing reporting positions met the arm's length standard and other requirements of section 482; or (iii) propose accuracy-related penalties under IRC section 6662.

54. In the course of the examination of Plaintiff's 2007 and 2008 tax years, the IRS also requested from Plaintiff information regarding the generic pharmaceutical product desloratadine and the assignment of a separate agreement relating to desloratadine to PITLP/LLC during the 2007 tax year. Since the assignment, PITLP/LLC has financed the development of desloratadine without any commercial success. Upon conclusion of its extensive examination of the events, entities and transfer pricing positions with respect to desloratadine, the IRS did not propose an adjustment to Plaintiff's income or otherwise challenge Plaintiff's tax reporting position.

55. Plaintiff timely filed consolidated Federal income tax returns for its 2009, 2010, 2011, and 2012 tax years and made payments to the IRS in accordance with the contractual

arrangements described above and in the amounts shown on the tax returns for the 2009, 2010, 2011, and 2012 tax years within the time period prescribed by law.

56. The IRS conducted routine civil examinations of Plaintiff's Federal income tax returns for the 2009, 2010, 2011, and 2012 tax years. The IRS relied heavily on hindsight to conduct a second audit and reopen issues previously examined and unadjusted during the examination of Plaintiff's 2007 and 2008 tax years. The IRS asserted deficiencies in tax and later made assessments with respect to the previously described transactions and arrangements, allocating all or virtually all of the income from United States sales of generic OTC omeprazole to Plaintiff. Plaintiff has fully paid the assessed amounts of tax, interest, and penalties to the IRS for the 2009, 2010, 2011, and 2012 tax years.

57. By letter dated May 5, 2015, the IRS designated for litigation the issues pertaining to generic OTC omeprazole for the 2009 and 2010 tax years.

58. On June 11, 2015, Plaintiff timely filed claims for refund for the 2009 and 2010 tax years, seeking refunds of overpaid Federal income taxes, penalties, and assessed interest, plus statutory interest thereon as allowed by law.

59. On June 7, 2017, Plaintiff timely filed claims for refund for the 2011 and 2012 tax years, seeking refunds of overpaid Federal income taxes, penalties, and assessed interest, plus statutory interest thereon as allowed by law.

60. By certified letters dated August 18, 2015, the IRS disallowed the claims for refund that Plaintiff filed for the 2009 and 2010 tax years. No amounts of the requested refunds have been credited, remitted, refunded, or repaid to Plaintiff or to anyone on its account.

61. By certified letters dated July 11, 2017, the IRS disallowed the claims for refund that Plaintiff filed for the 2011 and 2012 tax years. No amounts of the requested refunds have been credited, remitted, refunded, or repaid to Plaintiff or to anyone on its account.

62. Plaintiff is and at all relevant times has been the sole owner of these refund claims and has made no assignment of the claims. No action on these claims has been taken by the Congress of the United States or by any departments of the Federal government, other than the actions of the IRS described above. No other suit or process is pending on the claims in any other court.

63. The statute of limitations on assessment under IRC section 6501 has expired for all tax years prior to the 2009 tax year.

### **IRS ADJUSTMENT THEORIES**

64. With respect to the generic OTC omeprazole transaction described above, the IRS denied Plaintiff's claims for refund based on a variety of theories asserted in its original determinations, some of which are inconsistent with each other and mutually exclusive.

65. First, the IRS contends that PITLP/LLC is a sham entity that must be disregarded for Federal income tax purposes (the "sham entity theory").

66. Second, the IRS contends that the Assignment Agreement should be disregarded because the assignment lacks economic substance for Federal income tax purposes (the "sham transaction theory").

67. Third, the IRS contends that the assignment-of-income doctrine applies to attribute income from the sale of generic OTC omeprazole from PITLP/LLC to LPC (the "assignment-of-income theory").

68. The sham entity theory, the sham transaction theory and the assignment-of-income theory are referred to herein as the “primary common-law theories.”

69. As an alternative to the foregoing primary common-law theories, the IRS contends that most of the income from sales of generic OTC omeprazole should be reallocated from PITLP/LLC to Plaintiff under IRC section 482 and the Treasury Regulations thereunder (the “Section 482 Alternative Theory”).

70. The adjustments to Plaintiff’s taxable income for the 2009, 2010, 2011, and 2012 tax years under the IRS’s primary common-law theories result from the reallocation of 100% of PITLP’s/LLC’s net income to Plaintiff. The adjustments to Plaintiff’s taxable income for the 2009, 2010, 2011, and 2012 tax years under the IRS’s Section 482 Alternative Theory results from the reallocation of nearly all of PITLP’s/LLC’s income to Plaintiff.

71. With respect to the adjustments related to generic OTC omeprazole, the IRS bases its assessments on its primary common-law theories, not the Section 482 Alternative Theory. Plaintiff paid the full amount of these assessments.

72. In addition, the IRS asserts mutually exclusive penalties for each of the 2009, 2010, 2011, and 2012 tax years under four alternative theories.

73. Under its primary common-law theories, the IRS asserts a 20% substantial understatement penalty, citing IRC sections 6662(a), 6662(b)(2), and 6662(d) (the “20% Substantial Understatement Penalty”).

74. Under its primary common-law theories, the IRS asserts an alternative 20% negligence or disregard of rules or regulations penalty, citing IRC sections 6662(a), 6662(b)(1), and 6662(c) (the “20% Negligence or Disregard Penalty”).

75. Under its Section 482 Alternative Theory, the IRS asserts a 40% gross valuation misstatement penalty, citing IRC sections 6662(a), 6662(b)(3), 6662(e)(1)(B)(ii), and 6662(h)(2)(A)(iii) (the “40% Section 482 Penalty”).

76. Under its Section 482 Alternative Theory, and in alternative to the 40% Section 482 Penalty, the IRS asserts a 20% substantial valuation misstatement penalty, citing IRC sections 6662(a), 6662(b)(3), and 6662(e)(1)(B)(ii) (the “20% Section 482 Penalty”).

77. Because the IRS could only assess one of these penalties, it chose to assess the greater 40% Section 482 Penalty. The IRS did not apply the 40% Section 482 Penalty to the amount the IRS claimed Plaintiff owed under its asserted Section 482 Alternative Theory, but instead applied it to the amount the IRS claimed Plaintiff owed under its asserted primary common-law theories. The 40% Section 482 Penalty cannot be sustained based on the primary common-law theories.

78. With respect to Plaintiff’s deductions for the 2011 and 2012 tax years of ¶ IV ANDA patent litigation defense costs, although the IRS did not dispute the amounts of the legal fees and expenses that Plaintiff paid or incurred defending against patent infringement lawsuits or that such costs are generally deductible under IRC section 162 as ordinary and necessary business expenses, the IRS denied the claims for refund on the basis that the amounts Plaintiff paid or incurred should be capitalized rather than currently deducted (the “capitalization theory”).

79. The IRS bases its capitalization theory on two arguments. First, the IRS contends that the “origin-of-the-claim” doctrine mandates capitalization because the “origin” of the patent infringement claims was Plaintiff’s filing of ¶ IV ANDAs. Second, the IRS contends that the regulations promulgated under IRC section 263 require capitalization because the patent

litigation defense costs were “transaction costs” that “facilitated” FDA approval of the ¶ IV ANDAs.

80. Based on its capitalization theory, the IRS reduced Plaintiff’s deductions for the 2011 and 2012 tax years by \$2,185,376 and \$7,062,889, respectively.

81. In addition, the IRS treated the adjustment to Plaintiff’s income based on its capitalization theory as a change in method of accounting requiring an IRC section 481 adjustment in the 2011 tax year increasing income for that year in the amount of \$12,651,062 (the “section 481 adjustment”).

82. The foregoing IRS theories and assertions are erroneous, illegal, and not grounds to keep Plaintiff’s money.

#### **COUNT ONE: 2009 TAX YEAR**

83. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 82, *supra*.

84. The IRS’s sham entity theory lacks factual and legal basis. The reasons include that PITLP/LLC was formed as part of Plaintiff’s intended internationalization of its business operations and that PITLP/LLC conducted bona fide business activities.

85. The IRS’s sham transaction theory lacks factual and legal basis. The Assignment Agreement did not lack economic substance under the standards set forth in the regulations promulgated under IRC section 482, which render the common-law economic substance doctrine inapplicable to the assignment transaction. Even if the common-law doctrine applied, the assignment of the Contract possessed non-tax substance and satisfies both the objective and subjective prongs of the economic substance doctrine.



86. The IRS's assignment-of-income theory lacks factual and legal basis. The reasons include that the assignment-of-income doctrine does not apply, that the Assignment Agreement shifted ownership of the rights and obligations imposed by the Contract to PITLP/LLC, and that the assignment of the Contract was not an anticipatory assignment of income.

87. The IRS's Section 482 Alternative Theory, which allocates nearly all of the income of PITLP/LLC to Plaintiff, is unreasonable, arbitrary and capricious, an abuse of the IRS's discretion, without factual basis, and legally erroneous, and fails to produce an arm's-length result. Respective payments and incomes of PITLP/LLC and Plaintiff from the Contract and transactions related to the sale and distribution of generic OTC omeprazole reflected arm's-length results under the principles of IRC section 482 and the regulations promulgated thereunder.

88. The IRS's 40% Section 482 Penalty and 20% Section 482 Penalty do not apply. Those penalties are inapplicable because the IRS's Section 482 Alternative Theory is erroneous and contrary to law and therefore there was no valuation misstatement. Even if the IRS's Section 482 Alternative Theory were not illegal and erroneous, the IRS's 40% Section 482 Penalty and 20% Section 482 Penalty do not apply because Plaintiff satisfied the requirements of IRC section 6662(e)(3)(B)(i), including that Plaintiff applied appropriate transfer pricing methods to price the assignment of the Contract and transactions related to the sale and distribution of generic OTC omeprazole in a reasonable manner and in good-faith reliance on EY's professional tax advice.

89. The IRS's 20% Substantial Understatement Penalty does not apply because there is no understatement of tax to which the penalty can apply, substantial authority existed for Plaintiff's tax treatment, and Plaintiff reasonably and in good-faith relied on EY's professional tax advice.

90. The IRS's 20% Negligence or Disregard Penalty does not apply because there is no negligence or disregard of the rules or regulations as those terms are defined in IRC section 6662(c), Plaintiff had a reasonable basis for its tax treatment, and Plaintiff reasonably and in good-faith relied on EY's professional tax advice.

91. Accordingly, with respect to the 2009 tax year Plaintiff is entitled to a refund of assessed and overpaid tax, penalties, and interest of \$37,221,289, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus interest thereon as provided by law.

#### **COUNT TWO: 2010 TAX YEAR**

92. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 91, *supra*.

93. Accordingly, with respect to the 2010 taxable year Plaintiff is entitled to a refund of assessed and paid tax, penalties, and interest of \$61,462,133, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus interest as provided by law.

#### **COUNT THREE: 2011 TAX YEAR**

94. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 93, *supra*.

95. The IRS's capitalization theory lacks factual and legal basis. The reasons include that a patent holder's legal rights to protect its patented drugs arise under the patent laws and not under the food and drugs laws, that the origin of the claim doctrine otherwise does not apply because regulations promulgated under IRC section 263(a) govern all issues related to capitalization of intangible assets and preempt preexisting common law principles, and that

under those regulations patent litigation defense costs do not facilitate the acquisition of a ¶ IV ANDA within the meaning of Treasury Regulation section 1.263(a)-4 and therefore the costs are not subject to capitalization.

96. The IRS's section 481 adjustment lacks factual and legal basis. Because the IRS's argument under its capitalization theory that Plaintiff's ¶ IV ANDA patent litigation costs must be capitalized is illegal and erroneous, the IRS's section 481 adjustment is likewise invalid.

97. Accordingly, with respect to the 2011 taxable year Plaintiff is entitled to a refund of assessed and paid tax, penalties, and interest of \$40,148,650, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus interest as provided by law.

#### **COUNT FOUR: 2012 TAX YEAR**

98. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 97, *supra*.

99. Accordingly, with respect to the 2012 taxable year Plaintiff is entitled to a refund of assessed and paid tax, penalties, and interest of \$24,730,253, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus interest as provided by law.

#### **COUNT FIVE: INTEREST NETTING**

100. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 99, *supra*.

101. To the extent there are overlapping underpayments and overpayments of tax for the tax periods at issue, Plaintiff is entitled to net interest in accordance with the interest netting provisions of IRC section 6621(d).

### **COUNT SIX: RELATED ADJUSTMENTS**

102. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 101, *supra*.

103. Plaintiff reserves the right to challenge or assert any setoffs or adjustments, correlative or otherwise, that flow from any calculations, positions of Defendant, changes in law or final determinations by this Court in connection with this case.

### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff respectfully requests:

(1) With respect to Count One, judgment in Plaintiff's favor on its claim for relief for the 2009 tax year against the Defendant in the amount of \$37,221,289, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus interest thereon as provided by law;

(2) With respect to Count Two, judgment in Plaintiff's favor on its claim for relief for the 2010 tax year against the Defendant in the amount of \$61,462,133, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus interest thereon as provided by law;

(3) With respect to Count Three, judgment in Plaintiff's favor on its claim for relief for the 2011 tax year against the Defendant in the amount of \$40,148,650, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus interest thereon as provided by law;

(4) With respect to Count Four, judgment in Plaintiff's favor on its claim for relief for the 2012 tax year against the Defendant in the amount of \$24,730,253, or such greater amount of

overpayment that may be determined to be due and owing Plaintiff, plus interest thereon as provided by law;

(5) With respect to Count Five, the benefit of IRC section 6621(d) in the calculation of interest;

(6) With respect to Count Six, the benefit of any setoffs or adjustments resulting from calculations, positions of Defendant, changes in law, or final determinations by this Court; and

(7) Plaintiff's costs and such other relief as this Court deems to be just and proper.

Dated: August 15, 2017

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